DMB

Display Date 6-26-02
Publication Date 6-27-02
Certifier G. Lanley

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for the administration of Type C medicated feeds containing chlortetracycline to cattle as a top dress on feed for the treatment of enteritis and pneumonia.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 48–761 for AUREOMYCIN 50, 90, or 100 (chlortetracycline) Type A medicated articles. The supplemental NADA provides for the administration of Type C medicated feeds containing chlortetracycline to calves, beef and nonlactating dairy cattle as a top dress on feed to deliver 10 milligrams (mg) chlortetracycline per pound of body weight daily. These medicated feeds are used for the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline. The supplemental NADA is approved as of January 24, 2002, and the regulations are amended in 21 CFR 558.128 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

cv0181

NADA 48-761

NPR

Section 558.128 is also being amended to relocate a recently assigned withdrawal time (64 FR 23539, May 3, 1999) to the "Limitations" column of the table describing conditions of use. This is being done to improve the readability of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning January 24, 2002, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.128 is amended by redesignating paragraphs (a), (b), and (d) as paragraphs (b), (c), and (e), respectively; by adding new paragraphs (a) and (d); and by revising newly redesignated paragraphs (b) and (e) to read as follows:

§ 558.128 Chlortetracycline.

(a) *Specifications*. Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride.

(b) *Approvals*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 046573, 053389, and 066104: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 017519: 50 g/lb of Type A medicated article.

* * * * *

(d) *Special considerations*. (1) In milk replacers or starter feed; include on labeling the warning: "A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal."

(2) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

(3) When manufactured for use as in paragraph (e)(5)(iv) of this section, include on labeling the warning: "Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials."

(e) Conditions of use—(1) *Chickens.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Chickens: For increased rate of weight gain and improved feed efficiency.	. . . . .	046573.
		Do not feed to chickens producing eggs for human consumption.	017519, 046573, 053389, 066104.
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	046573.
		2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	017519, 046573, 053389, 066104.
(iii) 200 to 400 g/ton	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	046573.
		2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	017519, 046573, 053389, 066104.
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d.	046573.
		2. Feed for 5 d; do not feed to chickens producing eggs for human consumption.	017519, 046573, 053389, 066104.

(2) *Turkeys.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
(iii) 400 g/ton	1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.
	2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.		017519, 046573, 053389, 066104.
(iv) 25 mg/lb of body weight	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	017519, 046573, 053389, 066104.

(3) *Swine.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing swine: For increased rate of weight gain and improved feed efficiency.		017519, 046573, 053389, 066104.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(ii) 50 to 100 g/ton	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group *E. Streptococci* susceptible to chlortetracycline.		017519, 046573, 053389, 066104.
(iii) 400 g/ton	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	017519, 046573, 053389, 066104.
(iv) 10 mg/lb of body weight	1. Swine: For the treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 017519.	017519, 046573, 053389, 066104.
	2. Swine: For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 d.	046573.

(4) *Cattle*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(ii) 0.5 mg/lb of body weight daily.	Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 046573: zero withdrawal time. To sponsor No. 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.
(iii) 0.5 to 2.0 mg/lb of body weight daily.	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplsmosis caused by *A. marginale* susceptible to chlortetracycline.	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(2) of this section.	046573.
(iv) 10 mg/lb of body weight daily.	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter. To sponsor No. 053389: 1 d withdrawal time. To sponsor No. 046573: zero withdrawal time. See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
	2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(v) 4,000 to 20,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(1) of this section.	046573.
(vi) 25 to 70 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.
(vii) 70 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	See paragraph (d)(1) of this section.	017519, 046573, 053389, 066104.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(viii) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 046573: zero withdrawal time. For sponsor 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.
	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 046573: zero withdrawal time. For sponsor 053389: 1 d withdrawal time.	017519, 046573, 053389, 066104.

(5) *Minor species*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 20 to 50 g/ton	Growing sheep; increased rate of weight gain and improved feed efficiency.		046573, 053389, 066104.
(ii) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.		046573, 053389, 066104.
(iii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by *P. multocida* susceptible to chlortetracycline.	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.	046573.
(iv) 10 mg/g of finished feed daily.	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. See paragraph (d)(3) of this section.	046573.

(6) *Chlortetracycline*. It may be used in accordance with this section in combinations as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii) Bacitracin methylene disalicylate in accordance with § 558.76.

(iv) Clopidol in accordance with § 558.175.

(v) Decoquinate in accordance with § 558.195.

(vi) Hygromycin B in accordance with § 558.274.

(vii) Monensin in accordance with § 558.355.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) Roxarsone in accordance with § 558.530.

(x) Salinomycin alone or with roxarsone in accordance with § 558.550.

(xi) Tiamulin in accordance with § 558.600.

(xii) Zoalene in accordance with § 558.680.

Dated: 5/29/02

May 29, 2002.

Andrew J. Beaulieu,
Acting Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S